

Remarks

Claims 87-100, 103-116 and 121-123 are pending. Support for the amendment to claims 87 and 121 can be found in the instant specification at paragraph [0054].

Rejection under 35 U.S.C. § 112, first paragraph

Claim 95 is rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement. Applicant traverses said rejection.

Applicant's previous response regarding the written description requirement and starch derivatives was considered by the Office, but subsequently stated that "no actual evidence was presented to support applicant's assertion that starch *derivatives* were well known in the art" (see, the August 12, 2009 Office Action, page 5, lines 1-5) (emphasis in original).

Applicant submits that starch derivatives were well known in the art at the time of filing. For example, the "Encyclopedia of Food and Color Additives," George A. Burdock, Volume I, A-E, 1997, 695-697 recites a number of well known starch derivatives, including hydroxyethyl starches, cationic starches, starch acetates, starch succinates, starch phosphates, hydroxypropyl starches, and etherified starches (Appendix A). The individual derivatives are described along with the properties of said derivatives.

It is well settled in the law that to meet the "written description" requirement all that is required is that a skilled artisan understands that the inventor was in possession of the claimed invention at the time of filing, and even if every nuance of the claims is not explicitly described in the specification, the adequate written description requirement is still met. *Ex parte Parks*, 30 USPQ2d 1234, 1236–37 (B.P.A.I. 1993). Clearly, starch derivatives and their properties were well known in the art at the time of filing and the skilled artisan, considering the present application, would be able to determine an applicable starch derivative. Accordingly, applicant is in compliance with the written description requirement.

Applicant respectfully requests the withdrawal of the rejection of claim 95 under 35 U.S.C. §112, first paragraph.

Claim Rejections under 35 U.S.C. § 102(b)

Claims 121 and 122 are rejected under 35 U.S.C. 102(b) as being anticipated by Nakatsuka et al. (U.S. Patent No. 4,076,846; hereinafter, Nakatsuka). Applicant traverses said rejection

Applicant has amended claim 121 to recite:

“A particle comprising alginate and a starch-emulsifier complex, wherein the starch-emulsifier complex is partially or completely insoluble.”

It is well established, as a matter of law, that a claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference. *Verdegaal Bros. v. Union Oil Co. of California*, 2 U.S.P.Q.2d 1051, 1053 (Fed. Cir. 1987).

Nakatsuka described a water-soluble, edible thermoplastic molding composition that includes a starch material, an inorganic salt of a protein, an organic plasticizer and an edible lubricant. A water-soluble material such as Nakatsuka's is mutually exclusive of applicant's particle that includes a partially or completely insoluble complex and as such, Nakatsuka cannot anticipate applicant's claim 121.

Accordingly, applicant respectfully submits that claim 121 is patentably distinguishable over Nakatsuka. Withdrawal of this rejection under 35 U.S.C. §102(b) is requested.

Claim Rejections under 35 U.S.C. § 103(a)

1. Claims 87-96, 98, 103, 104, 108-112, and 114 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kürzinger (U.S. Patent No. 6,303,175; hereinafter, Kürzinger) in view of Nakatsuka. Applicant traverses said rejection.

Claim 87 has been amended to recite:

“An animal feed composition comprising a particle, wherein such particle comprises alginate and a starch-emulsifier complex, wherein the alginate comprises from about 0.5 to about 2.0 percent by wet weight of the particle, the emulsifier comprises a ratio to the starch from about 1:10 to about 10:1, and the starch-emulsifier complex is partially or completely insoluble.”

It is initially noted that the Examiner has impliedly suggested that one skilled in the art considering Kürzinger and Nakatsuka would knowingly select alginate from a laundry list of gel formers and plasticizers from Kürzinger and Nakatsuka, respectively. It is unclear why one skilled in the art considering Kürzinger and Nakatsuka would knowingly select alginate from each list, especially when the favored gel former in Kürzinger is agar agar and the favored plasticizer in Nakatsuka is water or glycerol. The Examiner’s ability to know that one skilled in the art would select alginate from the lists is questionable and suggests that the Examiner has resorted to hindsight reconstruction in an attempt to produce a *prima facie* case of obviousness, which is legally impermissible.

With regards to the starch-emulsifier complex, according to the Examiner, the term “complex” has not been given a special definition in the instant application. Applicants vigorously disagree. As recited in paragraph [0054], the starch-emulsifier complex is in the form of a partially or completely insoluble complex. Accordingly, Nakatsuka teaches away from forming a partially or completely insoluble complex because Nakatsuka relates to the formation of a water-soluble material. It is impossible to have applicant’s partially or completely insoluble complex and still have a water-soluble material, which is required by Nakatsuka. Moreover, assuming Kürzinger intended the feed form to be insoluble, Nakatsuka teaches away from Kürzinger. If Kürzinger intended the feed form to be soluble, then Kürzinger also teaches away from forming applicant’s partially or completely insoluble complex.

Moreover, assuming Kürzinger intended the feed form to be insoluble, there is no reason for the skilled artisan to combine Kürzinger with Nakatsuka because Kürzinger teaches an insoluble product while Nakatsuka teaches a water-soluble product. The Examiner is respectfully reminded that prior art must be considered as a whole, and as such, the Examiner is not allowed to cherry-pick useful teachings from Kürzinger and useful teachings from Nakatsuka in an attempt to establish a *prima facie* case of obviousness. Based on the Examiner’s proposed combination, applicant questions, should the final product be insoluble per Kürzinger or water-soluble per Nakatsuka? This is an important question when you consider the reasonableness of combining two pieces of prior art and what the expectation of success will be. Assuming the final product of the Examiner’s proposed combination were insoluble, Nakatsuka would be rendered unsatisfactory for its intended purpose. As such, a *prima facie* case of obviousness cannot exist. See *In re Gordon*, 733 F.2d 900, 221 USPQ 1125 (Fed. Cir. 1984).

Assuming Kürzinger teaches a water-soluble product, there is no reason to believe that the combination of Kürzinger and Nakatsuka teaches a partially or completely insoluble complex, as claimed by applicant herein.

Therefore, the combination of Nakatsuka and Kürzinger fails to teach the invention claimed herein, and the Examiner has failed to present a *prima facie* case of obviousness in view of Kürzinger and Nakatsuka. Therefore, applicant respectfully requests that the rejection under 35 U.S.C. 103(a) in view of Kürzinger and Nakatsuka be removed.

2. Claims 87, 97-100, 103, 105-107, 113, 115 and 116 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kurzinger in view of Nakatsuka as applied to claims 87-96, 98, 103, 104, 108-112, and 114 above, and further in view of Villamar et al. (WO 02/00035; hereinafter, Villamar). Applicant traverses said rejection.

Villamar is directed to a bioactive food complex product, method for preparing a bioactive food complex product, and method for controlling disease. Notably, Villamar does not teach or suggest the inclusion of starch in the Villamar food complex and as such, Villamar completely fails to teach the starch-emulsifier complex claimed herein. Accordingly, Villamar does not cure the deficiencies of Kürzinger and Nakatsuka.

Thus, the Office has failed to present a *prima facie* case of obviousness for applicant's claims in view of Kürzinger, Nakatsuka, and Villamar. As such, applicant respectfully requests that the rejection under 35 U.S.C. 103(a) in view of Kürzinger, Nakatsuka, and Villamar be withdrawn.

Rejoinder of Method Claims

Applicant requests that when the product claims of the present invention are found patentable, all pending method of making and using claims are examined through the rejoinder procedure in accordance with MPEP §821.04. Rejoinder is proper when an application as originally filed discloses a product and the process for making and/or using such product, and only the claims directed to the product are presented for examination, when a product claim is found allowable, applicant may present claims directed to the process of making and/or using the patentable product for examination through rejoinder procedure in accordance with MPEP §821.04, provided that the process claims depend from or include all the limitations of the allowed product claims.

Conclusion

Applicants have satisfied the requirements for patentability. All pending claims are free of the art and fully comply with the requirements of 35 U.S.C. §112. It therefore is requested that Examiner Orwig, reconsider the patentability of all pending claims, in light of the distinguishing remarks herein and withdraw all rejections, thereby placing the application in condition for allowance. Notice of the same is earnestly solicited. In the event that any issues remain, Examiner Orwig is requested to contact the undersigned attorney at (919) 286-8089 to resolve same.

Respectfully submitted,



Tristan A. Fuierer
Reg. No. 52,926
Attorney for Applicants
Moore & Van Allen, PLLC
Telephone: (919) 286-8000
Facsimile: (919) 286-8199

APPENDIX A

regular corn. Such a starch, it was postulated, should be an excellent film former and might be spinnable into a fiber. Genetic research ultimately resulted in the commercial development of two corn hybrids, one containing about 55%, the other about 70% amylose. The high-amylose granules are smaller than those from regular or waxy maize corn and they often have unusual shapes. Some granules do not gelatinize or lose their birefringence even when boiled for a long time. However, they will gelatinize in dilute alkali or alkaline salts, or when heated in water under pressure at elevated temperatures. The solutions must be kept hot or the amylose quickly gels and retrogrades. The high amylose starches are used to produce sizes for textiles and to produce quick-setting confectionery gums.

In addition to genetic production of waxy and high-amylose starches, several methods have been developed to fractionate the starch from common yellow dent corn into amylopectin and amylose. At least one of these processes has been used on a commercial scale.

Active research programs are now being conducted into new methods to alter the genetic makeup of corn to produce starches which have the characteristics and functionality of the starch derivatives discussed below.

Starch derivatives

Since the starch molecule contains many primary and secondary hydroxyl groups, it can be modified by chemical derivatization.

Unlike the modifications thus far discussed, derivatization may or may not reduce the viscosity of the parent starch. Derivatization is used to impart different properties to the derivative than those of the parent starch. This allows the derivative to meet more effectively the requirements of specific end uses. Countless starch derivatives have been described in technical literature and in patents, but only a limited number are manufactured and used commercially.

The derivatization of starch differs from most chemical modifications of polymers in that the changes in properties are attained with very slight changes in the molecule itself. In fact, all commercial derivatives are prepared under such mild conditions (usually in aqueous suspensions) that the starch granules retain their integrity. This allows the products to be handled in processing and application in much the same manner as the common starches previously discussed.

Starch derivatives are almost always prepared by adding the desired reagent to an agitated suspension of corn starch in water. By adjusting the pH of the slurry with an alkali, and sometimes with a catalyst, the mild reactions proceed on the ungelatinized starch at only slightly elevated temperatures. After sufficient reaction time, the derivatives are recovered by filtration or centrifugation, washed with water, dried and packaged.

Two basic types of derivatives are prepared commercially

A. Crosslinked derivatives

Crosslinked starches are made to overcome the sensitivity of starch sols to shear and processing conditions. This is accomplished by treating starch in the granule state with trace amounts of difunctional agents capable of reacting with hydroxyl groups on two different molecules within the granule.

Reagents such as phosphorus oxychloride or sodium trimetaphosphate may be used as crosslinking agents. Very small amounts of these agents can exert a marked effect on the behavior of the cooked starch. The degree of crosslinking controls the rate and extent to which starch swells on cooking. Crosslinking decreases the sensitivity of starch sols to temperature, agitation and acids, improving resistance to loss in viscosity.

B. Stabilization derivatives

Starch is stabilized against gelling by using mono-functional reagents which react with hydroxyl groups on the starch to introduce substituent groups which interfere with intermolecular association between starch molecules. Certain reagents may also introduce specific functionality into starches, e.g., increasing their water combining capacity or viscosity or imparting a positive charge to the starch molecule.

Hydroxyethyl starches - To produce hydroxyethyl starch, a starch slurry is adjusted to an alkaline pH and a salt is added to suppress the tendency of the starch to gelatinize. Ethylene oxide in varying quantities is added slowly to the agitated slurry and allowed to react for the proper time. Most hydroxyethyl starches are also acid-modified to reduce their viscosity. The hydroxyethylated starch is recovered by filtration, washed and dried. The introduction of the hydroxyethyl group reduces the gelatinization temperature of the starch and results in clear, stable pastes. They are widely used in surface sizing and coating paper.

Cationic starches - Reaction of corn starch with tertiary or quaternary amines yields quaternary ammonium or amino alkyl starches. When dispersed, these starches yield positively charged particles that are strongly absorbed by negatively charged cellulose fibers in the manufacture of paper. Less starch is used; but, more importantly, nearly all of the cationic starch in solution is adsorbed by the paper, leaving very little in the effluent going to the waste disposal system. This greatly reduces the biological oxygen demand load. In addition, cationic starch promotes the retention of fillers and pigments in the sheet while reducing the loss of very fine paper fibers. The additional retained fiber and the ability of the starch to bond the cellulose fibers together give greatly increased internal strength to the sheet. This substantive characteristic of cationic starches makes them useful also as surface sizes and as the adhesive in pigmented coatings.

Starch acetates - Corn starch can be acetylated with acetic anhydride or vinyl acetate under carefully controlled conditions of pH, temperature and time. After reaction, the starch is isolated by filtration, washed and dried. Sufficient acetyl groups are introduced to prevent retrogradation of the starch paste. Acetylated starches are used to size textile warps, yielding tough, yet flexible yarns. The reduced tendency to congeal makes starch acetates easy to pump and to apply at the slasher.

Starch acetates are also used as food starches. For example, waxy maize starch can be crosslinked with phosphorus oxychloride and then acetylated with acetic anhydride or vinyl acetate to produce an excellent thickener, texturizer or stabilizer used in preparing a wide variety of products.

Starch succinates - The use of succinic anhydride instead of acetic anhydride yields starch succinates which are also used as thickening agents for foods. The 1-octenyl succinic ester is also prepared and has affinity for fats and oils superior to that of other derivatives.

Starch phosphates - Starch can be esterified with monosodium orthophosphate or sodium tripolyphosphate to yield starch phosphates which produce gels that are more stable than those produced from the parent starch. The phosphated starches are used mainly in preparing food products.

Hydroxypropyl starches - Propylene oxide added to an alkaline starch suspension reacts with the starch to yield hydroxypropyl derivatives. When made in accordance with 21 CFR 172.892, hydroxypropyl starch can be used in food products, while hydroxyethyl starch can be used only in food packaging and industrial applications.

Other starch derivatives - Starch can be etherified by treatment with acrolein or epichlorohydrin. Such ethers may then be esterified with either acetic or succinic anhydride. Starches are also esterified with phosphorus oxychloride and then etherified with propylene oxide.

Pregelatinized starches

Suspensions of most starches and starch derivatives can be gelatinized and dried to yield a broad variety of pregelatinized starches. These products can be dispersed in cold water with agitation to yield pastes comparable to those obtained by cooking the raw starch. The pregelatinized starches make possible the production of many unique food and industrial products that do not require heat for preparation. "Instant" adhesives and "instant" starch-based puddings are examples of these types of products. New types of cold-water soluble (CWS) starches are particularly well suited for applications in microwavable food products.